

Fault Diagnosis in CPAP and NIPPV Devices

BACKGROUND OF THE INVENTION

This invention relates to ventilation devices such as non-invasive positive pressure ventilation (NIPPV) and continuous positive airway pressure (CPAP) devices which function to supply a patient with a supply of clean breathable gas (usually air, with or without supplemental oxygen) at a prescribed pressure or pressures at appropriate times during the patient's breathing cycle. The specification discloses a method and apparatus for fault diagnosis in such devices.

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An example of a suitable device in which the invention may be included is the AutoSet® T device (ResMed Ltd., Australia), which may be used for treating sleep disordered breathing, such as Obstructive Sleep Apnea (OSA), as described in US Patent 5,704,345 (Berthon-Jones).

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A NIPPV or CPAP device typically includes a flow generator, an air filter, a mask, an air delivery conduit connecting the flow generator output to the mask, various sensors and a microprocessor-based controller. The flow generator may include a servo-controlled motor and an impeller. The sensors measure, among other things, motor speed, gas volumetric flow rate and pressure. The air delivery circuit is that portion of the device's airflow path comprising the air inlet, the filter, the flow generator, the conduit and the mask. The device may optionally include a humidifier in the air delivery circuit. The controller may include data storage means.

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One problem compromising the effective operation of such devices is that with time, the air inlet filter may become dirty, increasing the filter's resistance to the flow of air. It is known to provide a warning light which is activated after a given number of hours of operation of the device, to indicate that the filter should be cleaned or replaced. Such an approach does not take into account the fact that the rate of accumulation of dirt on the filter will depend on the environment in which the device is used. It may

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also be found that the patient may continue to use the device despite the warning light and thereby receive inadequate therapy. Importantly, the air delivery circuit may become partly or completely blocked for other reasons, without a warning being given.

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SUMMARY OF THE INVENTION

At a given rotational speed of the motor, and a given air delivery circuit pneumatic impedance, the flow generator will deliver gas at a particular pressure. By measuring 10 the resultant pressure for a range of motor speeds, for different circuit impedances, and with and without the humidifier, characteristic curves of the device may be obtained. If then the values of motor speed, flow rate and pressure are measured by transducers during operation of the device, the current pneumatic impedance may be calculated from the appropriate characteristic curve. It is therefore possible to estimate 15 the resistance of the air filter and thus more accurately indicate when the filter needs changing. Furthermore, partial or complete blockage of the air delivery circuit will also be capable of detection by such an arrangement.

An acceptable range of measured pressure values may be calculated for a given set of 20 conditions, defined, for example, by upper and lower characteristic curves. The motor speed may be increased to maintain an acceptable output pressure as a response to increased impedance, while a pressure outside an acceptable range may be indicative of the need to replace the filter.

25 Such an arrangement relies on the transducers providing correct information regarding the monitored parameters, and in accordance with preferred forms of the invention the existence of transducer fault conditions is also responded to by the system.

The invention therefore broadly resides in a method or apparatus in which, in each 30 case, acceptable and unacceptable regions for transducer values are chosen. During operation of the device, the transducer values are measured and compared with the predetermined regions. When the transducers are in unacceptable regions, corrective

action is taken, for example, by issuing a warning of the fault or shutting down the device.

Thus, in one form, the present invention provides apparatus for supplying breathable gas to a patient, including a gas flow generator, a gas delivery circuit, a controller having data storage means, sensors monitoring values of operational parameters of the apparatus, and fault detection means including at least one relationship stored in said data storage means, said relationship relating a combination of values of at least two of said parameters as indicative of a fault condition of said apparatus, said fault detection means further including means testing said at least two said monitored operational parameter values against said stored relationships and instigating a response upon detection of a fault condition.

Preferably, said monitored parameters include at least motor speed of the flow generator, gas flow rate and gas delivery circuit pneumatic pressure.

In the practice of this aspect of the invention, a device embodying the invention will before clinical use be subjected to a calibration routine in which the motor speed and air delivery circuit pneumatic pressure are varied, while measuring pressure and flow rate. From these measurements characteristic curves are determined and stored in the data storage means associated with the controller.

During clinical use, flow rate, pressure and speed are monitored. The appropriate characteristic curves and acceptable range of pressure are selected for the current set of operating conditions. The measured pressure is tested against the acceptable range, and if it lies outside that range, a fault is asserted. If a fault is asserted, an error message may be given on the output screen, an alarm given, or the machine may be shut down.

In other embodiments of the invention, all of the transducers (such as snore, flow and speed transducers) are tested against predetermined characteristic curves for fault conditions.

Further embodiments are described below in relation to CPAP apparatus, but will be understood as being applicable to any of the above described forms of ventilatory treatment or assistance.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1(a) to (d) illustrate possible configurations of a device employing a humidifier and a loop back box.

10 **Figure 2 CPAP Apparatus**

Figure 3 Desirable operating region for blower (a) high speed, and (b) low speed

Figure 4 Computer software block diagram

Figure 5 Pressure transducer fault regions

Figure 6 Flowchart: Detect pressure transducer stuck low

15 **Figure 7 Flowchart: Detect pressure transducer stuck high**

Figure 8 Flowchart: Detect flow transducer stuck low

Figure 9 Flowchart: Detect flow transducer stuck high

Figure 10 Flowchart: Detect snore transducer stuck low

Figure 11 Flowchart: Detect snore transducer stuck high

20 **Figure 12 Flowchart: Detect speed transducer stuck low**

Figure 13 Flowchart: Detect speed transducer stuck high

Figure 14 Flowchart: Detect stalled motor

Figure 15 Flowchart: Detect restricted motor

Figure 16 Software fault diagnosis regions

25 **Figure 17 Flowchart: Software fault diagnosis**

In the figures, the "D" symbol is a logical "and", the rectangle symbol is a block of code. The triangle symbol is a comparator, if the conditions are met, then the output is a logical "1", otherwise "0".

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

An example of a problem solved by the present invention is provided by the
5 Applicant's AutoSet® T device, which is provided with a "loop back" box which facilitates the optional connection of a humidifier into the air delivery circuit upstream of the pressure transducer. The arrangement is described in co-pending Australian patent application No. 71978/98 filed 18 June 1998 and is schematically illustrated in Figures 1(a) to (d) hereof.

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Figures 1(a) and (b) show the correct manner in which the loop back box and the humidifier are intended to be connected. In Figure 1(a) the humidifier is not used, and the loop back box connects the flow generator (F) to the internal conduit where the pressure sensor (T) is located. The mask (M) is connected to its outlet downstream of
15 the pressure sensor.

Typically the ventilatory assistance for CPAP or NIPPV treatment is delivered to the patient by way of nasal mask. Alternatively, a mouth mask, a full face mask or nasal prongs can be used. In this specification, any reference to a mask is to be understood
20 as incorporating a reference to a nasal mask, mouth mask, full face mask or nasal prongs.

In Figure 1(b) the humidifier (H) replaces the loop back box and gas correctly flows from the flow generator, through the humidifier, past the pressure transducer and thus
25 to the mask.

In order that the AutoSet® device be compatible with a large range of standard tubing, humidifiers and masks, the outlets all have the same size and shape. It is therefore possible to assemble the equipment incorrectly, as shown in Figures 1(c) and (d). In
30 Figure 1(c) neither the loop back box nor the humidifier is used, and the mask is attached directly to the outlet of the flow generator, thus by-passing the pressure sensor. In Figure 1(d) the mask receives no pressurised air. In either of these situations

the pressure transducer will give an incorrect indication of mask pressure and this may lead to a dangerous overpressure in an automatically adjusting device.

By monitoring the pressure transducer output in conjunction with motor speed this
5 dangerous condition can be detected and responded to. Boundary conditions of high
motor speed and low pressure, and low motor speed and high pressure, may be chosen
as indicators of a fault condition. The same conditions can also be used to assert a
fault in the case of a defective pressure transducer, and are described later in relation
to Figures 6 and 7.

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A similar approach enables a stalled motor condition to be catered for in the NIPPV
device without the use of devices such as fuses. A stalled motor will not generate any
pressure, and the feedback control loop to the servo unit will cause an increase in
motor current. Conventionally, a fuse or other cut-out device will be required to
15 protect the motor from overheating. If however, the motor parameters of motor speed
and a motor drive parameter such as a function derived from current are monitored, a
fault condition may be established. For example, if the motor parameter is greater than
80% and the motor speed remains below 4,500 rpm for 0.2 seconds, a "Stalled Motor"
condition exists. A "Restricted Motor" condition can also be defined, for example
20 where the motor parameter exceeds 95% and the motor speed is lower than 15,000
rpm, for at least 30 seconds.

The corrective action in these cases is to disable the motor and otherwise disable
operation of the machine until service can be performed, this mode being termed the
25 "service required" mode.

Malfunction of the motor speed transducer will impact on the detection of motor stall,
and on other fault detection functions which will be described below. In this
specification there is therefore also described the manner in which the invention may
30 be applied to the detection of motor speed transducer failure.

It will be seen that the invention can be put into effect with appropriate software, using the control electronics already provided in the machine, and therefore represents an economical solution to the diagnostic objectives.

5 *Advantages of the invention*

- The invention has a number of advantages over the prior art. Firstly, safety can be improved. The greatest proportion of CPAP treatment apparatus are for use in a non-clinical setting, in which environment a user is untrained to detect conditions indicative of faults. Such fault conditions can lead to the CPAP treatment apparatus being ineffective or even dangerous. For example, the flow generators used in certain modern CPAP treatment apparatus are capable of delivering pressures in excess of 30 cm H₂O, which may be required in certain situations, but excessive and potentially dangerous in others.
- 10 The costs, both direct and associated, of CPAP treatment apparatus which include the invention can be reduced. Certain hardware such as fuses and other analogue circuitry may no longer be required. Furthermore, it becomes cheaper for technicians to diagnose faults since the device may be interrogated by interfacing with the controller, reducing the need to remove casing during service. Interfacing may be done locally or 20 remotely, for example through a network. In a clinical setting, this may have the further advantage of reducing patient disturbance.

- 15 In the CPAP treatment device with fault diagnosis, usability is improved. It becomes possible to provide fault diagnosis and rectification information to those without 25 clinical or technical skills.

The invention may also be used to predict more accurately when faults may occur, for example, to predict when a flow generator air inlet filter may need changing, based on measurements of the motor load.

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In the specification, any reference to "operating parameters" is to be understood to relate to any form of data or state signal, transducer or actuator, and the mechanical

and electrical functions of component elements/apparatus of a CPAP apparatus. Any reference to "process" is to be understood to mean a unit of hardware and/or software which can perform a task or set of related tasks, for example, a fault detection process, a feedback control process, a pressure measurement process or a flow measurement
5 process.

Following the diagnosis of a current or potential fault occurring, the response may be one or more of the following: issuing a warning of the fault condition, recording a diary entry describing the fault condition, adjusting operating parameters and
10 switching between the functional and stand-by or stop modes, or switching the device to a service-required mode. The response may be immediate, or at some later period, for example, the morning following the sleep period during which the device was used.

15 Figure 2 shows a simplified schematic of a typical CPAP treatment apparatus. An impeller (1) is powered by an electric motor (2) using a servo (3) under the direction of a microprocessor-based controller (4). The supply of breathable gas is carried to the mask (5) through a flexible conduit (6). The apparatus has various switches (7), displays (8) and a number of transducers. The transducers monitor a number of
20 processes, for example: volumetric flow rate (10) (at a predetermined point in the flow path), pressure (11) (at a predetermined point downstream of the flow generator outlet or at the mask), snore (12), flow generator rotational speed (13) and motor parameter (14).

25 *The concept of an acceptable region: hardware operation*

There may be a relationship between the measured blower flow rate, f , and the measured blower output pressure, p , such that f decreases when p increases. It may be desired that for acceptable operation of the device, the parameter values be kept in a certain region. The function R for that process may be written:

Distinct functions may be determined for different conditions, for example, high and low motor speeds, as shown in Figures 3a and 3b. Alternately, the acceptable region could be defined by a 3-parameter model, $R = R(f, p, \omega)$, where ω is motor speed.

5 *Example of a logical test*

In a simple case, the acceptable region may be a rectangle, defined by two values of flow f_1 and f_2 and two values of pressure, p_1 and p_2 . If the estimates of the parameter values were $\{f, p\}$ then the test to diagnose a current fault may be, for example:

- 10 If $p > p_1$ and $p < p_2$ and $f > f_1$ and $f < f_2$ then the current operation region lies within the acceptable range.

Alternatively, the method may diagnose a fault if $\{f, p\}$ lay outside the acceptable range for an instant, or lay outside the desirable range for some duration.

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Computer software block diagram

- Advantageously, the invention is implemented in software. In this case, no additional hardware is needed. The fault detection software processes may be executed in conjunction with existing software. This is shown in Figure 4. The inputs to the controller (4) are analogue electronic signals indicative of the value of various sensors, transducers and other electronic circuitry. These are converted to digital signals. The hardware parameter values (41) are passed to one or both of the normal computer software processes (44) (for example, feedback control processes) and the fault diagnosis processes (43). Further parameters may be generated (42) (for example, flags) indicative of the operation of each of the software processes, and passed back into one or both of the software processes. In addition, the processes may generate hardware instructions (45) (for example, information to be displayed, or directions to shut down the operation of the CPAP device) which are converted to analogue electronic signals and passed to the relevant hardware.

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Fault diagnosis of each apparatus process may be executed as a distinct software process, or several apparatus processes may be monitored within a single software process.

5 PREFERRED MODE OF OPERATION

Processes monitored

In the preferred mode of carrying out the invention, in each device, a plurality of processes are monitored. These include:

Pressure transducer operation

10 Flow transducer operation

Snore transducer operation

Speed transducer operation

Motor operation

Breath and Apnea detection algorithms

15 Fault diagnosis process operation

Air filter operation

Correct assembly of air delivery circuit

Modes of fault diagnosis for these processes are described in the following

20 sections.

Pressure transducer

The invention may be used to detect whether the pressure transducers are correctly operating. A consequence of a failure of a pressure transducer (11) could be

25 overpressure or under-pressure to the mask and thus the patient. To detect such a failure condition, the transducer pressure is monitored (11) together with motor speed (13). The regions of faulty device operation are shown in Figure 5. Logical flowcharts indicating the decision process are shown in Figures 6 and 7.

30 If the sensed pressure remains below 2.0 cm H₂O (62) while the motor speed is above 12,000 rpm (61) for at least 0.3 seconds (65), a fault condition is signalled as a

"Pressure Transducer Low" failure (66). If neither condition is satisfied, a timer is reset (64).

In a similar way, if the pressure value remains above 15 cm H₂O (72) while the motor speed is below 4,500 rpm (71) for at least 0.3 seconds (75), that corresponds to a "Pressure Transducer High" failure (76). On detection of either form of pressure transducer failure, corrective action is taken to disable power to the motor (2) and a notification is given on a display. The user may then check all components in the air delivery circuit for an obstruction or an incorrect connection.

An additional embodiment is used for the pressure transducer fault diagnosis mode in conjunction with motor speed. The output from the pressure transducer is split into two signals. One signal, P_{high} remains unfiltered, whilst the other signal is low-pass filtered to become P_{low}. Each signal is tested to yield an output of "Pressure Transducer High", "Pressure Transducer Low" or "ok". The conditions for "high" and "low" are as described above. A signal which is neither high nor low is deemed to be ok. Unless the test result for both signals is "ok", a fault condition will be signalled. If the test result for both signals is "low", the fault condition is taken as an indication that the hoses are not connected.

Flow Transducer
A failure of the flow transducer (10) can cause errors in flow measurement, mask pressure measurement and signal processing (such as inspiratory flow flattening index, as taught in US Patent No. 5,704,345). This in turn may result in errors in the delivery pressure from the flow generator (1), compromising the efficacy of treatment. Logical flowcharts indicating the decision process are shown in Figures 8 and 9.

To detect such a fault, the flow transducer (10) signal is monitored together with motor speed (13). If the flow remains below 5 % full scale deflection (f.s.d.)(82) while the motor speed is less than 4,800 rpm (81) for more than five seconds (85), the fault condition is signalled as "Flow Transducer Low" failure (86). If neither condition is satisfied the counter is reset (84). In a similar manner, if the flow generator flow

remains above 95% f.s.d. (92) with the motor speed less than 4,800 rpm (91) for more than 5.0 seconds (95), the fault of "Flow Transducer High" is signalled (96).

- On occurrence of either fault condition, the patient is notified on a display, and in
- 5 addition, the mask pressure will be increased over some time, for example, five minutes, to a predetermined level, in this case, the 95% centile of the previous session. However if that pressure value would be invalid by representing a dangerous overpressure, the pressure will be limited to 10 cm H₂O.

10 *Snore Transducer*

A failure of the snore index transducer can cause errors in the snore measurement and the calculated snore index. Such errors result in consequential errors in the treatment pressure delivered by the flow generator (1), again possibly compromising the efficacy of treatment. Logical flowcharts indicating the decision process are shown in

15 Figures 10 and 11.

- To detect a failed snore transducer the snore transducer signal (12) and motor speed (13) are sampled. If the snore index signal remains below 5% f.s.d. (102) with the motor speed greater than 11,000 rpm (101) for more than two seconds (105), a "Snore
- 20 Transducer Low" failure is signalled (106). If neither condition is satisfied the counter is reset (104). If the snore transducer (12) signal remains above 95% f.s.d. (112) while the motor speed is less than 6,000 rpm (111) for more than two seconds (115) a "Snore Transducer High" failure mode occurs (116).
- 25 The corrective action that can be taken is to notify the user of the occurrence and, if the flow generator (1) is generating a pressure, attempt to increase the pressure over some time, for example 5 minutes, to a predetermined level, for example, the 95% centile of the previous session. If that pressure value is invalid by representing a dangerous overpressure, the pressure will be limited to 10 cm H₂O.

Motor Speed Transducer

An incorrect motor speed may impact upon functions arising from the pressure transducer (11), flow transducer (10) and snore transducer (12). Logical flowcharts indicating the decision process are shown in Figures 12 and 13. Detection of a failure of the motor speed transducer (13) is achieved by monitoring the speed (13) together with the sensed pressure (11) and flow (10) and the motor drive parameter (14). If the motor speed remains below 6,000 rpm (121) while the motor drive parameter is above 15% (122) and either the pressure is above 8.0 cm H₂O (123) or (125) the flow is greater than 75% f.s.d. (124), this set of conditions being true for more than one second (128), then a "Motor Speed Low" failure is signalled as occurring (129). If any of the conditions are not met, the counter is reset (127).

If the motor speed remains above 18,000 rpm (131) while the motor drive is below 5% (132) and (136) either the pressure is below 2.0 cm H₂O (133) or (135) the absolute flow is less than 10 l/min (134) for more than one second (138), a "Motor Speed High" failure is signalled as occurring (139).

The corrective action that can be taken is to notify the user of the occurrence and, if the flow generator (1) is generating a pressure, attempt to increase the pressure over some time, for example 5 minutes, to a predetermined level, for example, the 95% centile of the previous session. If that pressure value is invalid by representing a dangerous overpressure, the pressure will be limited to 10 cm H₂O.

25 *Motor*

As noted earlier, a stalled motor will not generate any pressure. Such a condition can occur if the impeller (1) is jammed, for example. The feedback control loop from the flow generator (1) to the servo unit (3) will cause an increase in the power delivered to the motor (2), the increase continuing until maximum power is supplied. A consequence can be overheating of the motor to the extent that insulation or windings

fail and the motor must be replaced. Flowcharts describing the operation for "stalled" and "restricted" motor are shown in Figures 14 and 15 respectively.

- A motor failure condition is detected by monitoring the motor speed (13) and motor drive parameter. If the motor parameter is greater than 80% (142) and (143) the motor speed remains below 4,500 rpm (141) for 0.2 seconds (145), a "Stalled Motor" condition exists (146). If any of the conditions are not met, the timer is reset (144). In a similar way, if the motor parameter exceeds 95% (152) and the motor speed is lower than 15,000 rpm (151), occurring for more than 30 seconds (155), then a "Restricted Motor" condition exists (156).

The corrective action is to disable power to the motor and otherwise disable operation of the machine until a service can be performed, this mode being termed the "service-required" mode.

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Pneumatic Performance

- In another embodiment, the method may be used to check the overall pneumatic, or air delivery, performance of the apparatus. The relevant regions are shown in Figure 3, being the desired operating region ζ_d and fault regions ζ_{f1} , ζ_{f2} . The operating regions are a function of pressure (p), flow (f) and motor speed (ω). If, the operational state of the device lies in region ζ_{f1} , there are several possible causes:

Dirty filter

Internal air path blockage in the CPAP apparatus

Leak in the internal air path of the CPAP apparatus

25 Flow generator failure

Faulty speed sensor

Faulty flow sensor

Faulty pressure sensor

30 Possible responses include:

Issuing a warning advising that the filter needs changing

Switching the apparatus to service-required mode

If the operational state of the device lies in region ζ_2 , there are several possible causes:

- 5 Faulty speed sensor
- Faulty flow sensor
- Faulty pressure sensor

The response would be to switch the device to the service required mode.

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The embodiments described earlier may be used in conjunction with the current embodiment, to distinguish which of the sensors may be faulty.

Fault diagnosis operation

- 15 The events "pressure transducer stuck high" and "pressure transducer stuck low" are mutually exclusive. Similarly the flow, snore and motor speed transducers have mutually exclusive conditions. In another embodiment of the invention, the fault diagnosis processes tests whether mutually exclusive conditions have been deduced and signals an error in fault diagnosis if that event occurs.

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Breath and Apnea detection processes

- Figure 16 shows the operating regions for the breath and apnea detection processes. These processes detect the presence of breathing by the user and the occurrence of apneas, these two events being mutually exclusive. During normal operation of the CPAP device, either one or the other of these events ought to be detected. In this case, these two events lie within non-intersecting regions of ζ_d (Figure 16). If the current operating region of the device lies outside both these two regions, then some kind of error has occurred and an error is asserted. A flowchart for this fault detection process is shown in Figure 17. While the device is operating the "Breath Detection" and "Apnea Detection" processes are monitored. The fault detection process will assert a fault when either of the following two conditions occur:
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- 30

- Apnea and Breath are asserted simultaneously
- Neither Apnea nor Breath are asserted for a predetermined period.

While particular embodiments of this invention have been described, it will be evident
5 to those skilled in the art that the present invention may be embodied in other specific
forms without departing from the essential characteristics thereof. The present
embodiments and examples are therefore to be considered in all respects as illustrative
and not restrictive, the scope of the invention being indicated by the appended claims
rather than the foregoing description, and all changes which come within the meaning
10 and range of equivalency of the claims are therefore intended to be embraced therein.